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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF ILLINOIS

TERRY PAULSEN, an individual, Plaintiff, vs. ABBOTT LABORATORIES, an Illinois corporation, individually, TAP PHARMACUETICAL PRODUCTS, INC, ABBOTT LABORATORIES as a Successor in Interest of TAP Pharmaceutical Products, Inc. (TAP); ABBVIE, INC, Delaware corporations, as successor in interest of TAP and TAKEDA PHARMACEUTICALS USA, INC, a Delaware corporation, as Successor in Interest to TAP. Defendants.	Case No.: 1:15-cv-04144 **PLAINTIFF PAULSEN'S SECOND AMENDED COMPLAINT FOR DAMAGES**

Plaintiff, by and through her attorneys, ALAN S. LEVIN, M.D., J.D., TESFAYE W. TSADIK, ESQ. and MARTIN A. DOLAN, ESQ., on behalf of herself, hereby files this Second

Amended Complaint.

1. The Plaintiff, TERRY PAULSEN (hereafter "PAULSEN" or "Plaintiff"), is an individual and at all times relevant hereto was and is a resident of the State of Georgia. PAULSEN was injected with *Lupron* on two occasions, February and March 2004.

DEFENDANTS

2. The Defendant ABBOTT LABORATORIES ("Abbott") is an Illinois corporation with its principal place of business at 100 Abbott Park Road, Abbott Park, Illinois. Abbott is sued herein both individually for its own acts and omissions and as Successor in Interest for acts and omissions of defendant TAP PHARMACUETICAL PRODUCTS, INC. ("TAP")

3. At all relevant times, Defendant TAP PHARMACEUTICAL PRODUCTS, INC. was a joint venture between Abbott and TAKEDA CHEMICAL INDUSTRIES, LTD ("Takeda"). TAP was a Delaware corporation which was dissolved and merged on June 30, 2008 with Takeda Pharmaceuticals America, Inc. and was named as a defendant in this action for the purpose identifying its acts & omissions for the benefits of its successors in interest defendants. All services of processes will be made to all of its successor in interest defendants who have been named in this complaint and not to TAP.

4. The Defendant TAKEDA PHARMACEUTICALS U.S.A., Inc. ("TPUSA") formerly known in 2001 as TAKEDA PHARMACEUTICALS AMERICA, INC. (The name of the Surviving Corporation after it merged with TAP) and in 2012 as TAKEDA PHARMACEUTICALS NORTH AMERICA, INC., is a Delaware corporation which is a wholly owned subsidiary of TAKEDA CHEMICAL INDUSTRIES, LTD., with its headquarters located in One Takeda Parkway, in Deerfield, Illinois 60015. TPUSA is liable as a defendant in this lawsuit as a successor in interest to TAP PHARMACUETICAL PRODUCTS, INC.

5. In 1977, Takeda Chemical Industries, Ltd. and Abbott Laboratories entered into a joint venture agreement, governed under the Illinois law, entitled Basic Agreement which acted as platform for the initial development phase human pharmaceutical compounds, in the United States and Canada. In 1985, Abbott and Takeda entered into a supplemental agreement to the Basic Agreement which reaffirmed and continued their joint venture and by creating TAP, a closely held Delaware Corporation, with, each owning and controlling a fifty percent (50%) stake in TAP.

6. TAP's purpose, pursuant to the joint venture agreement, was to develop, manufacture, market and sell human pharmaceutical products for the American and Canadian markets including *Lupron* which the subject of this action**.** TAP focused its marketing efforts on securing *Lupron* use and sales by physicians; including physicians within the states of New York, Georgia, and California.

7. On March 19, 2008, Abbott and Takeda entered into an agreement to dissolve their joint venture operated through TAP. In this transaction, Abbott and Takeda evenly divided the value of the joint venture with Abbott, acquiring all assets, employees, and liabilities related to *Lupron*. After the acquisition, TAP's all *Lupron* related activities and operations merged with Defendant Abbott. The *Lupron* operation, thereafter, continued for many years as one of the departments of Abbott. At all relevant times, Plaintiff alleges that TAP was created and existed solely because of the joint venture agreement between Abbott and Takeda and TAP operated not for the benefit of the corporation but rather for the benefit of those who joined together to form it -the owners. The business and management and affairs of TAP was controlled, dominated by Abbott and Takeda through joint appointment of management, directors, and committees and the shareholders voting agreement.

8. In July 2008, TAP, with its 50% of its remaining asset, was merged into Takeda Pharmaceuticals North America, Inc. which subsequently changed its name to Takeda

Pharmaceuticals U.S.A, Inc. After this merger TAP dissolved as a corporation

9. Defendant Abbott is, therefore sued herein for its own acts and omissions as well for all acts and omission of TAP as successor in interest to TAP based on the theory that it assumed directly all liabilities related to TAP and/or under theory of merger and /or continuation of TAP's *Lupron* operations. Defendant TPNUSA is also, sued herein as a successor in interests to all acts and omission of TAP under the theory of merger.

10. In December 2012, AbbVie spun off from Abbott taking the sales, employees, and liabilities associated with *Lupron*. AbbVie is, therefore liable, as a successor in interest of TAP, for all acts, omissions of TAP in connection with *Lupron* product based on the theory that it assumed directly all the liabilities related to *Lupron* and /or under a theory of merger with Defendant Abbott, and/or continuation of TAP's *Lupron* operations by Defendant Abbott.

11. References herein to the knowledge, actions and/or omissions of the "Defendant", "Defendants" or "TAP" specifically include Abbott jointly, severally, acting in concert, with or through others, their partners, agents, servants and/or employees, the companies they own, control, or for whose actions they are responsible.

FACTUAL BACKGROUND

12. *Lupron* was developed in or around 1985 and was first approved by the United States Food and Drug Administration ("FDA") for the palliative treatment of prostate cancer on January 26, 1989.

13. *Lupron* was approved by the FDA as a treatment for endometriosis on or about October 22, 1990, and as a treatment for anemia associated with uterine fibroids on or about March 30, 1995.

14. In April 1998, TAP submitted a report to the FDA in which researchers disclosed that they were "concerned" because more than one-third of the women they studied who took

Lupron did not "demonstrate either partial reversibility" or "a trend toward return" of bone mass in the six months after they stopped taking the drug.

15. Upon information and belief, as early as October 22, 1990, and for more than a decade, TAP and Abbott were aware of the continued bone loss incurred by users of *Lupron*, but took no corrective action, gave no adequate warning, and did not take the drug off the market.

16. In 2001, the FDA approved *Lupron* "add-back therapy", designed to counteract the harmful bone-depleting effects of *Lupron*, which involves the use of a progestin-based hormone replacement known as norethindrone.

17. TAP and Abbott should have known, based upon the state of knowledge that existed at the time regarding *Lupron,* and on generally accepted medical and research standards and principles, that serious long-term health problems are associated with the use of *Lupron*, including, but not limited to, an increased risk of significant permanent bone mineral density loss, early development of osteoporosis, and osteopenia; neurological, ophthalmologic, pituitary, and metabolic complications; and muscle pain, joint pain, and debilitating fatigue. TAP and Abbott failed to adequately apprise Plaintiff or Plaintiff's physicians of such problems and risks, as well as a litany of other side effects.

18. The prescribing information provided to physicians and pharmacists and the Patient Information Pamphlet did not adequately warn of the risks of significant permanent bone mineral density loss, early development of osteoporosis, and osteopenia in female patients.

19. Defendants TAP and Abbott made certain affirmative claims which were distributed and circulated to the medical profession, and to the general public, through advertising, literature, promotional documents, brochures and other materials, which represented *Lupron* to be a safe and efficacious drug treatment for women with certain gynecological problems such as endometriosis and uterine fibroids.

20. Upon information and belief, Defendants Abbott and TAP misrepresented and concealed the risks inherent in the use of *Lupron* regarding the severity and permanent bone loss in their applications for FDA approval, and in representations to physicians and the consuming public.

21. PAULSEN was injected with *Lupron* obtained by her treating physician from drug detail persons working for Abbott on two occasions beginning on or about February 2004 and ending on or about March 2004. Upon information and belief, *Lupron* was prescribed to treat endometriosis. PAULSEN's physician told her that the Abbott detail person, who visited his office, characterized *Lupron* as appropriate, safe and effective for patients with her medical condition. According to PAULSEN, neither she nor her physician were made aware, by Abbott or TAP, of the serious threat to her bone health posed by the use of *Lupron* for her endometriosis. Defendant Abbott knew that the representations made to Plaintiff's physician would be transmitted to Plaintiff. Plaintiff relied on the representations made by Abbott employee.

22. Shortly after being injected with *Lupron*, PAULSEN began to develop serious bone and joint pain. PAULSEN was treated for this joint pain and was subsequently diagnosed with severe joint arthropathy in April of 2008. She was later diagnosed with osteoporosis in May of 2010. Among other related maladies, PAULSEN suffers from chronic joint pain, muscle pain, and fatigue.

23. Plaintiff had no facts sufficient to place her on inquiry notice of the claims set forth herein within two years of the filing of the previous complaint. Plaintiff did not discover and could not have discovered through the exercise of reasonable diligence the causal connection between her injures and the negligent conduct of Defendants herein.

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FIRST CAUSE OF ACTION vs. AGAINST ALL DEFENDANTS
(Strict Products Liability)

24. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in paragraphs "1" through "23" inclusive, as if expressly rewritten herein.

25. At all times herein mentioned, the Defendant Abbott and TAP, jointly, severally, acting in concert, with or through others, their partners, agents, servants and/or employees, the companies they own, control, or for whose actions they are responsible, manufactured, compounded, tested, distributed, recommended, marketed, labeled and packaged, merchandized, advertised, promoted, sold, purchased, prescribed, and administered the *Lupron* and the Plaintiff used, took, or injected with.

26. *Lupron* was expected to and did, in fact, reach consumers without substantial change in the condition in which *Lupron* was produced, formulated, manufactured, sold, distributed, labeled and packaged and marketed by the Defendants.

27. At all times herein described, *Lupron* was in an unsafe, defective, and inherently dangerous and was hazardous to users, and specifically to the Plaintiff in the condition in which the *Lupron* was produced, manufactured, sold, distributed, labeled and packaged, and marketed by the Defendants.

28. At all times herein mentioned, the Defendants knew or had reason to know that *Lupron* was defective and unsafe.

29. At the time Plaintiff was injected with *Lupron*, the drug was being used for the purposes and in a manner normally intended by Defendants.

30. Neither the Plaintiff, through her own reasonable care, nor her physician could have discovered the defects herein mentioned or perceived their danger any sooner than they did discover such defects. Defendants did intentionally and/or negligently fail to warn the Plaintiff and others of the dangers associated with the use of *Lupron*.

31. As a direct and proximate result of the defective and unsafe condition of *Lupron*, Plaintiff was caused to sustain severe and grievous personal injuries, as described herein, including but not limited to negative effects on bone mineral density, osteoporosis, and/or osteopenia.

32. By reason of the foregoing, Plaintiff has been damaged in the sum of FIVE MILLION DOLLARS ($5,000,000.00) in compensatory damages and FIVE MILLION DOLLARS ($5,000,000.00) in punitive damages.

SECOND CAUSE OF ACTION vs. AGAINST ALL DEFENDANTS

(Strict Products Liability- Failure to Warn)

33. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in paragraphs "1" through "32", inclusive, as if expressly rewritten herein.

34. Defendants Abbott and TAP, jointly, severally, acting in concert, with or through others, partners, agents, servants and/or employees, the companies they own, control, or for whose actions they are responsible, manufactured and/or supplied *Lupron*, and placed Lupron into the stream of commerce in a defective and unreasonably dangerous condition such that the foreseeable risks exceeded the benefits associated with the design and/or formulation of the product.

35. The *Lupron* designed, manufactured, labeled and packaged and/or supplied by Abbott and TAP was not accompanied by proper warnings to physicians, the medical community, or to women, regarding all possible side effects, health concerns and risks associated with the use of *Lupron*. The warnings and information which were given to the medical community and women consumers did not accurately reflect the severity and permanence of symptoms, duration, scope or severity of the potential side effects, health concerns, and risks of *Lupron.*

36. Defendants Abbott and TAP, each failed to perform testing which would have shown *Lupron*'s potential to cause serious severe and permanent bone damage side effects, health

concerns and/or risks.

37. Defendant Abbott and TAP also failed to engage in adequate post-market surveillance and to issue appropriate post-marketing warnings and/or instructions regarding the potential severe and permanent bone loss side effects, health concerns, and/or risks associated with *Lupron,* of which Defendants Abbott and TAP were or should have been aware. To the contrary, Defendant Abbott and TAP continued to promote *Lupron* aggressively without these warnings and/or instructions.

38. Had adequate warnings or instructions regarding permanent bone loss side effects been provided, Plaintiff would not have used, taken, or received administrations of *Lupron*, and would not have suffered the harmful side effects, other injuries and damages described herein.

39. As a direct and proximate cause of the defective condition of *Lupron* which Defendants Abbott and TAP, jointly, severally, acting in concert, with or through others, their agents, servants and/or employees, the companies they own, control, or for whose actions they are responsible, designed, developed, manufactured, produced, tested, sold, labeled and packaged, marketed, supplied and/or distributed, and the absence of adequate and timely warnings about the potential severe, permanent bone loss risks of the drug, Plaintiff suffered those injuries and damages as described herein, including but not limited to negative effects on bone mineral density, osteoporosis, and/or osteopenia.

40. By reason of the foregoing, Plaintiff had been damaged in the sum of FIVE MILLION DOLLARS ($5,000,000.00) in compensatory damages and FIVE MILLION DOLLARS ($5,000,000.00) in punitive damages.

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THIRD CAUSE OF ACTION vs. AGAINST ALL DEFENDANTS

(Negligence)

41. Plaintiff repeats, reiterates, and realleges each and every allegation of this Complaint contained in paragraphs "1" through "40" inclusive, as if expressly rewritten herein.

42. At all times relevant to this action, Abbott and TAP, each had a duty to exercise reasonable care, and to comply with the then existing standards of care, in their preparation, design, research, development, manufacture, inspection, labeling, marketing, promotion and sale of the *Lupron* drug which Abbott and TAP introduced into the stream of commerce, including a duty to ensure that users like Plaintiff Terry Paulsen would not suffer from unreasonable, dangerous or untoward adverse side effects. Abbott and TAP, each of them, had a duty to provide a reasonably safe product.

43. At all times relevant to this action, Abbott and TAP, each of them had a duty to warn all health care providers and consumers of the risks, dangers, and adverse side effects of *Lupron* that each was aware.

44. At all times relevant to this action, Abbott and TAP each of them knew or reasonably should have known that *Lupron* was unreasonably dangerous and defective when used as directed and as designed, including but not limited to the following particulars:

a. increased risk of significant severe and permanent bone mineral density loss;

b. early development of permanent osteoporosis and osteopenia;

c. muscle pain, joint pain, debilitating and chronic fatigue.

45. Based on what they knew or reasonably should have known as described above, each of the Defendants deviated from the standard of care and breached their duty and were otherwise negligent in one or more of the following particulars:

a. in formulating, analyzing, designing, fabricating manufacturing, supplying, distributing, advertising, promoting, packaging, marketing, selling and recommending *Lupron* in its defective condition, Defendant Abbott and TAP knew or should have known;

b. failing to identify, eliminate, and /or reduce the risks and hazards associated with the intended and foreseeable use of the *Lupron*;

c. failing to advise Plaintiff and her physician the dangers associated with the use of Lupron.

46. As a direct and proximate result of the aforementioned negligence of Defendants Abbott and TAP, jointly, severally, acting in concert, with or through others, and the companies they own, control, or for whose actions they are responsible, Plaintiff was caused to sustain severe and grievous injuries, including but not limited to negative effects on bone mineral density, osteoporosis, and/or osteopenia.

47. By reason of the foregoing, Plaintiff has been damaged in the sum of FIVE MILLION DOLLARS ($5,000,000.00) in compensatory damages and FIVE MILLION DOLLARS ($5,000,000.00) in punitive damages.

FOURTH CAUSE OF ACTION vs. AGAINST ABBOTT LABORATORIES

(Fraudulent Misrepresentation)

48. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in paragraphs "1" through "47", inclusive, as if expressly rewritten herein.

49. At all relevant times, the Defendant Abbott, through their agents, servants and/or employees, the companies they own, control, or for whose actions they are responsible, made false and fraudulent misrepresentations to the medical community and to users of Lupron through its labeling, advertising, marketing materials, detail persons, seminar presentations, publications, and notice letters, beginning in the 1990's and continuing into the 2000's. These misrepresentations

include, but are not limited to, assurances that *Lupron* had been tested and found to be a safe and effective treatment for, among other things, eliminating the incidence and symptoms of endometriosis and uterine fibroids.

50. Early February 2004, a few days before her injection with Lupron, an Abbott drug detail person personally contacted Plaintiff's physician, Dr. Perry at his office located at 1199 Prince Avenue, Athens, Georgia and expressly represented the safety and effectiveness of Lupron that would effectively treat Plaintiff's reproductive tract ailment, that there is no long term adverse effect.

51. Defendant knew or should have known the public representation as well as the specific representation to Plaintiff's physician and through him to plaintiff was false. Defendant Abbott knew, or should have known, that serious long-term health problems are associated with the use of *Lupron*, including, but not limited to, an increased risk of significant bone mineral density loss, early development of osteoporosis, and osteopenia; and/or muscle and joint pain and debilitating fatigue. Defendants failed to adequately apprise Plaintiff or Plaintiff's physicians of such problems and risks, as well as a litany of other side effects.

52. Nevertheless, Defendant Abbott willfully, wantonly and recklessly disregarded the falsity of their statements and omissions; made these representations fraudulently and deceitfully, with the intent that they would be relied upon by inducing Plaintiff to seek and accept *Lupron* as treatment for endometriosis and/or uterine fibroids. Defendant Abbott's acts and/or omissions evince a callous, reckless, willful, and depraved indifference to the life, health, safety and welfare of the drug's intended users, including the Plaintiffs herein.

53. At the time Defendant Abbott made its misrepresentations, users of *Lupron*, including Plaintiff Paulsen herein, could not, by the exercise of their own reasonable care, discover the falsity of Defendants' misrepresentations and instead, Plaintiff reasonably believed the

representation made by Abbott publicly and specifically through its employee be true and relied on them to make her decision to receive the *Lupron* injection treatment.

54. Defendants sought and in fact did obtain FDA approval of Lupron in its defective form, in part based upon Defendants' fraudulent misrepresentations, and Defendants inserted *Lupron* into the stream of commerce, which caused harmful effects to *Lupron's* users, including the Plaintiff herein.

55. Defendant Abbott knew or should have known that *Lupron* had been insufficiently tested, lacked adequate warnings, and would lead to serious injury amongst its users, including Plaintiff, who would rely on Defendant Abbott's misrepresentations to her detriment. Defendants thereby breached their duty to Plaintiff, to users of *Lupron*, and to the medical community, including Plaintiff's physicians.

56. As a direct and proximate result of her detrimental reliance on Defendant's fraudulent conduct and misrepresentations, disseminated jointly, severally, acting in concert, with or through others, and the companies they own, control, or for whose actions they are responsible, the Plaintiff was caused to sustain permanent, severe, and grievous personal injuries, as set forth herein, including but not limited to negative effects on bone mineral density, osteoporosis, and/or osteopenia.

57. By reason of the foregoing, Plaintiff has each been damaged in the sum of FIVE MILLION DOLLARS ($5,000,000.00) in compensatory damages and FIVE MILLION DOLLARS ($5,000,000.00) in punitive damages.

FIFTH CAUSE OF ACTION vs. AGAINST ALL DEFENDANTS

(Negligent Misrepresentation)

58. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in paragraphs "1" through "57" inclusive, as if expressly rewritten herein.

59. The Defendants, Abbott and TAP, individually or jointly, severally, acting in concert, with or through others, their partners, agents, servants and/or employees, the companies they own, control, or for whose actions they are responsible, had a duty to make accurate representations to the medical community, the Plaintiff herein, and the general public. Defendants, Abbott and TAP, each one them, represented, among other things, that *Lupron* had been tested and found to be safe and effective for the use as an injectable drug for the treatment of endometriosis.

60. Defendants Abbott and TAP, each knew or should have known that the drug had been insufficiently and/or inappropriately tested, that it lacked adequate warnings, and/or that it created a high risk of unreasonable and dangerous side effects and health risks, including but not limited to significant and permanent loss of bone mineral density, early development of osteoporosis, chronic, and debilitating pain.

61. Because Defendants, Abbott and TAP, each one of them, did not accurately disclose *Lupron's* serious permanent side effects and health risks to the medical community, the Plaintiff, and the general public, Defendant Abbott and TAP, each one of them, negligently misrepresented *Lupron's* actual, unsafe condition. The treating physicians of Plaintiff herein detrimentally relied on Defendants' misrepresentations in treating Plaintiff with *Lupron*, and Plaintiff herself detrimentally relied on these misrepresentations in accepting the treatment with injection of *Lupron*.

62. As a direct and proximate result of her detrimental reliance on the negligent misrepresentations by Defendants Abbott and TAP Plaintiff Paulsen was caused to sustain severe and grievous personal injuries, including but not limited to negative effects on bone mineral density, osteoporosis, and/or osteopenia.

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63. By reason of the foregoing, Plaintiff has been damaged in the sum of FIVE MILLION DOLLARS ($5,000,000) in compensatory damages and FIVE MILLION DOLLARS ($5,000,000) in punitive damages.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, TERRY PAULSEN demands judgment against Defendants, individually or jointly & severally, on each cause of action, for damages in the amount prayed for, with interest, together with the costs and disbursements of this action, and any and all further relief this Court deems just and proper.

DATED this 6th day of July, 2018.

BY: /s/ Alan S. Levin

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Attorneys for Plaintiff

CERTIFICATE OF SERVICE

I hereby certify that on July 6, 2018, I electronically filed the foregoing **PLAINTIFF PAULSEN'S SECOND AMENDED COMPLAINT FOR DAMAGES** with the Clerk of the Court using the CM/ECF system, which will send notification to all counsel of record.

/s/ Alan S. Levin
Attorney for Plaintiff Terry Paulsen